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Original Research

Clinical Study of Research Based Innovated Ksharsutra Technique (RIKT) With Special Reference to Complex Fistula in Ano

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***ABSTRACT*:**
Introduction: Fistula is a common disease occurring in Anorectal region.Sushruta, the father of surgery has included this disease in to "Ashtamahagada" due to its difficulty of treating. Fistula in Ano is a track lined by granulation tissue which opens in anal canal or rectum and externally on skin around anus. Clinically there are two type of fistula. 1. Simple fistula 2-Complex fistula. Complex fistulas are those fistulas where more than 1/3rd of Sphincter is involved. There is no technique for complex fistula with definitive cure rate. The techniques like Fistulotomy, Fistulectomy, Fistulectomy with Primary Reconstruction, Advancement flap does not very promising and it involves damage to Sphincter which can lead to Incontinence whereas Ksharasootra (SMS) therapy is a worldwide popular system now in Ayurveda. Sphincter sparing procedure like LIFT, VAAFT, Anal fistula Plug, Fibrin glue, OTSC clip , Filac laser ,Stem cells have success rate of around 50°/o to 70°/o. Fistulectomy is gold standard for Simple Fistula with success rate close to 95°/o, but in case of Complex Fistula, the surgeon can't afford to cut more than 1/3rd of sphincter leading to incontinence. There are high chances of recurrence and incontinence in available treatment methods. To combat the problem RIKT is taken for treatment. **Aim & Objectives**:- To evaluate the Research Based Innovated Ksharasootra Technique (RIKT) clinically in the treatment of Complex fistulae at Rana Piles Hospital, Sirhind Punjab. **Material & Methods**: The Study was carr ied out totally in 50 patients of Complex fistulae having high anal fistula with more than 1/3 rd of sphincter involved and noted as Recurrent 39 cases, multiple tracks 41, Horse shoe 17, Supralevator 15, and Associated with abscess 15 cases. **Discussion**: The patients were thoroughly screened by Physical examination, Lab Test, MRI and Proctoscopy. Follow up was done for a period of 6 weeks. Before and after clinical findings were recorded.The RIKT is a technique in which the intersphincteric space was treated with Ksharasootra; the probe is inserted from external to internal opening, open in intersphincteric space by cautery and applied the SMS from external opening till intersphincteric plane opens. In this way intersphincteric plane was opened and kept it open till it heals by secondary intention (best method of healing for infected wounds). Post operative care has been taken by maintaining the intersphincteric plane Applied Jatyadi oil in anal canal for a considerable period. In this treatment it is noted that anatomical importance of intersphinteric space is important. **Result & Conclusion**:- The results were shown that Complex Fistula were healed in 44 patients, having RIKT success rate close to 94 percent. On generated data RIKT is most effective technique than today's other conventional technique with sparing sphincter control and incontinence.

Keywords: Complex Fistula, Research Based Innovated Ksharasootra Technique (RIKT}, Inter sphincteric Plane, Sphincter Control, Incontinence.

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INTRODUCTION:

Fistula is a common disease occurring in Anorectal region. Acharya Sushruta, The father of surgery has included this disease in to "Ashtamahagada" due to its difficulty of treating. Fistula in ano is a track lined by granulation tissue which opens in anal canal or rectum and externally on skin around anus. Clinically there are two type of fistula. 1. Simple fistula 2. Complex fistula.

Complex fistula are those fistula where more than 1/3rd of Sphincter is involved. There is no technique for complex fistula with definitive cure rate. The techniques like Ksharsutra in Ayurveda and fistulotomy , Fistulectomy ,Fistulectomy with Primary Reconstruction, Advancement flap in modern science are not very promising and it involves damage to Sphincter which can lead to Incontinence. Sphincter sparing procedure like LIFT, VAAFT, Anal fistula Plug, Fibrin glue, OTSC clip , Filac laser ,Stem cells have success rate of around 50% to 70%. Fistulotomy is gold standard for Simple Fistula with success rate close to 95%, But in case of Complex Fistula you can't afford to cut more than 1/3rd of sphincter leading to incontinence.

Treatment for a perianal fistula is determined by the anatomy of the fistula. There are 4 types of fistulae:

1) Intersphincteric
2) Transsphincteric
3) Suprasphincteric
4) Extrasphincteric.

The diagnostic approach to examining a patient with a fistula is with magnetic resonance imaging (MRI) or endoscopic ultrasound, or examination by a surgeon under anesthesia. Asymptomatic Crohn's fistulae usually require no treatment; however, internal fistulae (eg, gastrocolic, duodenocolic, or enterovesicular) that cause severe or persistent symptoms should always be treated surgically.

Surgical treatment is guided by the type of Anorectal fistula, with the goal of primary healing. There are high chances of recurrence and incontinence in available treatment methods. So a clinical study has been carried out at Rana Piles Hospital, Sirhind (Punjab), to treat complex fistula by Research Based Innovated Ksharsutra Technique (RIKT).

AIM:

To study the effectiveness of Research Based Innovated Ksharsutra Technique (RIKT) in the management of complex fistula in ano.

REVIEW OF LITERATURE:

The father of surgery Acharya Sushruta, has included the disease Fistula (Bhagandara) as one among Ashtamahagada. At first it appears as pustule around anus (Gouda) and when it bursts out it is called Bhagandar. Sushrutacharya included in to ashtamahagada due to its difficulty in to complete cure. Which is having same challenge for todays advanced medical fraternity also.

Classification of fistula in ano is of immense importance, as it gives accurate description of the anatomy of the course of the fistulous tract which is helpful to a surgeon in planning the operative cure of the disease. They are usually classified based on relation to the anal sphincter complex.

In 1934 Milligan & Morgan classified the fistulas into High fistulas-those in which the internal opening lies above the anorectal ring and Low fistulas-those in which the internal opening lies below the anorectal ring.

It was a simple classification but was abandoned as the tract information was not forth coming, leading to recurrences.

Park classified the fistulas into sub-mucosal, intersphincteric, supra-sphincteric and extra-sphincteric. These terms are quite informative in relation to the sphincter apparatus.

1)The Submucosal fistula is not involving any sphincter and is simplest to manage.

2)Intersphincteric fistula traverses through the internal sphincter.

3)Trans sphincteric fistulas pass through both the internal and external sphincters and are further subdivided into low and high depending on the part of the external sphincter muscle. The low fistulas involve only the outer part of the external sphincter while high fistulas involve greater part of the external sphincter. Incontinence would be a complication of this group.

4)Supra sphincteric fistula typically arise at the dentate line internally, cross above the internal sphincter but below the puborectalis and exit on to the peritoneal site.

5)Extra sphincteric fistula are rare and do not involve the sphincter complex. They arise from above the

denatate line into the ischio-rectal fossa. These are non cryptogenic in nature and have different management strategies.
Supra sphincteric and extra sphincteric described by Park are very rare to find. They are mostly due to wrong treatment by surgeon.

The drawback of this classification is that it is clinically very difficult to classify them and so the need for classification oriented investigations in form of trans rectal ultrasound or Magnetic resonance imaging of perineum. So that the surgeons widely divided fistulas into simple fistula and complex fistula.
Broadly for better understanding the fistulas below the anorectal rings were simple fistula and above the anorectal ring were complex fistula. Complex fistula are those fistula where more than 1/3rd of Sphincter is involved. All the recent procedures having less or more certain drawbacks . High recurrence rate and incontinence is commonest drawback seen in all recent procedures.

INCLUSIVE CRITERIA=

1) Patients having high anal fistula with more than 1/3 rd of sphincter involved.
2) Recurrent , Multiple tracks , Horse shoe shaped, Supralevator , Associated with abscess were selected.

EXCLUSION CRITERIA=

1) Patients having tuberculosis, immuno compressed, simple fistula i;e low anal fistulas, cancer etc. were excluded.
2) Patients having irregular follow-up also excluded.

MATERIAL AND METHOD:

1) MATERIAL-

Premedication-

Inj. Aciloc
Inj. Emset
Inj.Cefotaxime 1gm given as premedication

Anesthesia-

Inj. Propofol 2mg/kg body weight for general anaesthesia.

Ksharsutra-

Specially designed kshar sutra is used as knife to open intersphincteric space towards anus, by rubbing and simultaneous cutting internal sphincter. It is beaded with knots, knots were put on thread,so that when we rub there in proper curettage. Knots were put on barbour linen 20thread at equal intervals and then coatings were done as per standard.
H2O2 3ml **+ Betadine** 7ml for chemical cauterization.

Normal saline-

Used for irrigation and separating unhealthy granulation from healthy tissue.

Jatyadi oil-

Used at end of procedure to promote healing and coating the tissue to protect it from bacteria and faecal impaction.

2) METHODOLOGY:

Principle-

As our understanding of anatomy is increasing, importance of intersphinteric space is being recognized more and more, deep post anal space of Courtney was considered very important for posterior fistula.
But with more understanding of anatomy now it is proven that deep post anal space is more important in complex posterior cryptoglandular fistula than deep post anal space.
Focus seem to be shifting from treating deep post anal intrsphinctric space than deep post anal space.

PROCEDURE:

1) Diagnosed high anal fistula patients were selected.
2) RIKT is a technique in which we open intersphincteric space by kshar sutra has been explained to patient and their relatives.
3) Written informed consent were taken for RIKT study.
4) Under General anaesthesia following procedure has been done.
5) Inserted a probe from external to internal opening , intersphincteric space laid open by cautery in intersphincteric space once probe.
6) Then inserted a Ksharsutra from internal opening till intersphincteric plane.
7) Opened it by moving Ksharsutra by rubbing few circular fires of internal sphincter and mucosa has been opened and pus was drained out.
8) By This method we will open intersphincteric space and we will keep it open till it heals by secondary intention.(Best method of healing for infected wounds.)
9) Now curetted thoroughly from external opening till intersphincteric plane by curette.
10) Flushed it with H2O2 3ML+Betadine 7ml followed by curetted by a gauze. (Passed it through external opening till intersphincteric space.)
11) Gauze moved it in clockwise and anti-clockwise in half circle,by this method we sloughed out unhealthy tissue.
12) Then flushed with normal saline through it so that all unhealthy tissue is flushed out.

13) Jatyadi oil applied at the end on all wound.

POST OPERATIVE:
Post operative care has been taken by to maintaining -

1) To Dry external opening and intersphincteric plane by sterilised ear buds twice a day.
2) After rubbing and cleaning applied Jatyadi oil in anal canal.

INVESTIGATIONS =

1) Digital rectal examination has been done for assessment of fistulas in ano as localization of internal or primary opening
2) Introduction of Hydrogen peroxide + Betadine from external opening with or without the use of methylene blue is another method of localization of the primary crypt has been done.
3) Endosonology has been done for exact track localisations.

ASSESSMENT CRITERIA:
All the patients were assessed on the basis of post operative improvement in the course of healing of fistulous track.

1) SUBJECTIVE CRITERIA
All the patients were instructed to keep Dry external opening and intersphincteric plane by sterilised ear buds twice a day.
After rubbing and cleaning applied Jatyadi oil in anal canal.
Advised regular follow up after 7 days for 6 weeks.

2) OBJECTIVE CRITERIA
All the course of healing of fistulous track were examined and noted thoroughly by Surgeon.

CRITERIA ASSESSSMENT FOR OVERALL:
1) All the patients of complex fistula were assessed on the basis of mainly 5 types of their clinical appearance.
1) Recurrent 2) Multiple tracks
3) Horse shoe shaped 4) Supralevator
5) Associated with abscess
6) Healing of fistulous track and its progress were noted till the end of 6 weeks.
7) At the end of 6 week all the findings were noted and summarized in tabular form for evaluation of RIKT.

OBSERVATIONS:
All the observations noted at the end of the 6 week.
Though complex fistula having multiple interconnected with each others so broadly we have categorized in the types.
So number of patients and types did not matched with the figure.
Total patients were 50 in numbers. Including all interconnections.
We have tried to simplified the data for better understanding of surgeon.

Types of fistula	No. of patients	Healed completely	Not Healed	Percentage %
Recurrent	**39**	**38**	**01**	**97 %**
Multiple tracks	**41**	**39**	**02**	**95.12 %**
Horse shoe shaped	**17**	**16**	**01**	**94.11 %**
Supralevator	**15**	**14**	**01**	**93 %**
Associated with abscess	**15**	**14**	**01**	**93 %**

LIMITATIONS:
1) This study has been conducted for outcome of this technique so only complex fistula and its healing pattern were noted.
2) It is observational study so that data was generated and evaluated on the basis of end of the treatment.
3) This technique is first one in which ksharsutra has been used and at the same time sparing of sphincter control achieved in patients, it is highlighting marker for our study.
4) All clinical sign symptoms were noted but limitation of work we did not explained in a observations.
5) Data can be fractionalized and can be presented differently i;e further scope of study.

DISCUSSION:
The management of complex fistula in ano needs complete knowledge of perineal anatomy and pathophysiology. The sphincter complex is the nodal factor and the anatomical plane of the area is important. The first line management should be sphincter saving where sphincter division is avoided.
Techniques like Ksharsutra in Ayurveda and fistulotomy , Fistulectomy ,Fistulectomy with Primary

Reconstruction, Advancement flap are not very promising and it involves damage to Sphincter which can lead to Incontinence. Sphincter sparing procedure like LIFT, VAAFT, Anal fistula Plug, Fibrin glue, OTSC clip , Filac laser ,Stem cells have success rate of around 50% to 70%.

When above modalities fail. Newer technique need to be evaluated. So Aggressive surgical approach with Ayurvedic Ksharsutra technique is combined for better success rates in complex fistulas, research based innovated ksharsutra technique has more than 90% success rate so RIKT is having highest cure rates than any other available procedures with sparing sphincter control.

Although we have summarized the data there is further scope of study to evaluate the above procedure for adaptation. Application of ksharsutra with deep knowledge of anorectal fistulas are the highlighting features of this research work.

CONCLUSION:

Based on our study ,we have been conclude that the RIKT (Research Based Innovated Ksharsutra Technique) is effective and having more than 90 % success rate than todays other available procedure with sparing sphincter control.

RESULTS:

RIKT (Research Based Innovated Ksharsutra Technique) is effective and having highest success rates to treat complex fistula with sparing sphincter control.

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